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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,071	02/08/2002	John D. Pazienza	1133279-0017	4638

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,071

Applicant(s)

PAZIENZA ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 and 23-37 is/are allowed.
- 6) ☒ Claim(s) 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/094,402.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The amendment filed 1/7/04 has been entered as Paper No. 7. Changes to the specification and claims have been approved by the examiner.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of European Application No. 97201799.0 has been filed in parent Application No. 09/094,402, filed on June 10, 1998.
3. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/511,481 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers. At this time, the certified copy of European Application No. 98201446.6 has not been received in the parent Application No. 09/511,481. Once the certified copy has been filed with 09/511,481, applicant may simply indicate that the filing has been made in response to this office action. No certified copy will then be required for the current application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 17 now requires that "the stent undergoes substantially no foreshortening during expansion". There is no support for this limitation in the original specification and therefore constitutes new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 17, 18, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Colgan et al. (USPN 6,264,689).

Colgan et al. discloses a stent with all the elements of claim 17. See Figures 14A-14B, columns 1-2, lines 66-9 and column 9, lines 16-25 for a stent having a generally cylindrical main body comprising a plurality of helical segments (6 strands), wherein at least one helical segment crosses another helical segment at wrap joints (254) and cross joints (256). See column 9, lines 20-25 for the stent having an expanded diameter of 14mm and being crimped to fit within a 7 French catheter. Because a 7 French catheter has an outer diameter of 2.3mm, the stent within it

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has to have an even smaller diameter. Therefore, the stent has an expanded diameter that is about 6 times the crimped diameter. See column 2, line 5 and column 9, lines 20-21 for the stent undergoing substantially no foreshortening during expansion. The word “substantially” is broad in scope, and because the specification does not define what is encompassed by “substantially”, it is broadly interpreted to mean a considerable amount.

Claim 18, see Figures 14A-14B for helical segments contracting and expanding when the stent is crimped and expanded. The contraction/expansion occurs by the changing shape of the cells formed by the crossing helical segments (strands).

Claims 21 and 22 are product-by-process claims, and according to MPEP § 2113, these claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The patentability of a product does not depend on its method of production, but on the product itself. The wires of Colgan et al. are certainly capable of being produced from laser cutting a tube of the required diameter.

Allowable Subject Matter

8. Claims 1-16 and 23-37 are allowed.

Response to Arguments

9. Applicant's arguments with respect to claims 17, 18, 21, 22 have been considered but are moot in view of the new ground(s) of rejection. Additionally, applicant's arguments filed 1/7/04 are not persuasive with respect to the following:

10. Applicant argues that the stent of Colgan shown in Figure 2A is a chain-link fence in the form of a tube consisting of a single piece of woven wire. This is not correct. Colgan clearly

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discloses that the stent of Figure 2A and other embodiments comprises a tubular body with a body wall structure having a pattern of geometric cells defined by a series of *elongate strands*, not a single piece of woven wire. The strands are helically wrapped about each other to form wrap joints and cross joints.

11. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., helices are connected by struts cut from a solid tube and stent is made up of connective undulations) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner